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The New Age of the Nagoya Protocol

David E. Schindel[1], Tania Bubela[2], Joshua Rosenthal[3], David Castle[4], Pierre du Plessis[5], Robert Bye[6], PMCW[7]

1 *National Museum of Natural History, Smithsonian Institution, Washington D.C., U.S.A.* **2** *School of Public Health, University of Alberta, Edmonton, Alberta, Canada* **3** *Division of Epidemiology and Population Studies, Fogarty International Center, Washington D.C., U.S.A.* **4** *University of Victoria, British Columbia, Canada* **5** *CRIAA SA-DC, Windhoek, Namibias* **6** *Instituto de Biologia, Universidad Nacional Autónoma de Mexico, México City, Mexico* **7** *Participants of the Mexico City Workshop: Medicinal plant barcoding and natural health products research: moving the debate forward on access and benefit sharing*

Corresponding author: *David E. Schindel* (schindeld@si.edu)

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Abstract

The entry into force of the Nagoya Protocol of the Convention on Biological Diversity will lead to new legislation and regulations that could change international collaborative research in biology. This article suggests a new approach that researchers can use in negotiating international Access and Benefit Sharing agreements under the Protocol. Research on medicinal plants is used as a case study because it is a domain with many competing stakeholders involving non-commercial and commercial research, as well as national and international commercial markets. We propose a decision-based framework to aid all participants as they negotiate ABS agreements for non-commercial biodiversity research. Our proposed approach promotes transparency and builds trust, reflects the principles in the *Convention on Biological Diversity*, and respects and protects the interests of biodiversity rich developing countries. This approach is an alternative to often-used adversarial approaches.

Keywords

Nagoya Protocol, Access and Benefit Sharing, DNA barcoding, medicinal plants, Convention on Biological Diversity, international agreements

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Introduction

The Nagoya Protocol (full name: *The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*; CBD Secretariat 2011) was approved by the Conference of the Parties to the *Convention on Biological Diversity* in October 2010 after eight years of negotiation (see analyses in EU Parliament Directorate General for Internal Policy 2013; Laird and Wynberg 2012; Kamau et al. 2010). As of 14 July 2014, the Protocol had been ratified by the required 51 countries which triggered its entry into force on 12 October 2014, partway through the Conference of the Parties to the Convention on Biological Diversity (CBD) in Korea. From that point forward, all Parties to the Nagoya Protocol are expected to create implementing legislation and regulations. This will be no easy process and is likely to deepen long-standing divisions among stakeholders in this domain. Developing countries that are rich in biodiversity but poor in terms of wealth and technology are pinning great hopes on the economic value of their biodiversity. In implementing the Nagoya Protocol, these countries might tend towards restrictive legislation that erects barriers against perceived risk of misappropriation of their genetic resources by any and all potential users. Such protectionist regulations are not unreasonable responses but when the costs, benefits and unintended consequences are considered, they may not be the optimal route to long-term benefits and development. Specifically, a protectionist regulatory system might reduce unapproved uses of genetic resources but it may also erect barriers to the development and sharing of knowledge about national biodiversity. Such systems may limit access to training (in-country or international), technology transfer, capacity building and other benefits that international partnerships can offer. They also reduce incentives for the conservation of biodiversity when it is more profitable in the short-term to convert land to agriculture and other purposes than it is to study, preserve, and sustainably develop biodiversity. It need not be so.

Background

Prior to the *Convention on Biological Diversity*'s (CBD) entry into force in December 1993, biological samples flowed across most international borders with relative ease. Regulations focused on customs control for taxation purposes and to prevent the import of pests, pathogens and protected endangered species. The motivation for international transport of scientific samples varied widely. Some transfers were part of biological exploration for taxonomic and ecological studies and for education and public display, predominantly in developed country institutions. Some were part of academic biodiscovery projects on biological systems, including human diseases. The end-products were scholarly publications, museum exhibits, some capacity-building and training, and expanded awareness of and appreciation for biodiversity. Others were driven by the desire to develop commercial markets for cash crops, foods, medi-

cines, textiles, and the broad range of products that could be derived from living organisms. Some began as the former and developed into the latter, either by conscious design or through serendipitous discoveries of the economic value of particular species. Researchers in industrialized countries reflect back on those open borders as a golden age of research and development. Memories of this early period are markedly different in many biodiversity-rich countries whose species were exported and created wealth for others with little, if any, return. The term "biopiracy" is often used to summarize this view.

Rather than considering biodiversity as the common heritage of humankind, the CBD affirmed Sovereign States' control over the utilization of their genetic resources. The CBD established three objectives: (1) the conservation of biological diversity; (2) the sustainable use of its components; and (3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. In September 2002, Parties to CBD called for the establishment of an "International Regime" that would achieve the third objective, setting in motion eight years of negotiations that culminated in approval of the Nagoya Protocol. Under the Nagoya Protocol, obligations to share benefits are triggered by the utilization of genetic resources and are based on a requirement for potential users to seek Prior Informed Consent (PIC) and negotiate Mutually Agreed Terms (MAT) with governments and local indigenous peoples that hold traditional knowledge associated with the genetic resources.

Some countries enacted laws during the negotiation process to protect their genetic resources by requiring PIC and MAT. Such laws, empowered by the CBD and now clarified by the Nagoya Protocol, could create a level playing field for joint activities with mutual benefits between industrialized and developing countries. However, many of these laws have gone beyond international regulation to also cover domestic access. New barriers in some countries limit access by in-country researchers to genetic resources, especially in areas inhabited by local communities or indigenous peoples (Beas-Rodriguez 2012). This suggests that mistrust over the misappropriation of genetic resources without due compensation can apply to both domestic and international research.

The likely entry into force of the Nagoya Protocol stimulated several efforts to facilitate the process of drafting ABS agreements. For example, the Swiss Academy of Sciences provided a useful ABS management tool with best practices (Stratos, Inc. 2012) and developed a template for non-commercial ABS agreements with model clauses that negotiators could plug into the template (Biber-Klemm, Martinez and Jacob, 2010). We suggest, however, that one-size-fits-all solutions, even those with selections of model clauses, (a) will be difficult to use, (b) may not align with the specific interests of the parties, and (c) may not satisfy national ABS and other laws. The numbers and types of participating stakeholders will be highly variable, their concerns and sensitivities will depend on many factors, and the capabilities and ambitions of participating researchers will be important but unpredictable factors. Indeed, use of off-the-shelf agreements runs the risk of including spurious terms and conditions or, conversely, omitting terms and conditions that are required to meet the needs and

interests of the parties. It also misses a critical opportunity offered by the negotiating process - the chance to engage potential partners in meaningful discussions that promote the development of long-term, trust-based research relationships (Cragg et al. 2012; Geary et al. 2013).

Non-commercial biodiversity research (sometimes termed 'basic'), both domestic and international, is becoming a casualty in the struggle over potential monetary benefits from commercialization of genetic resources and derivative products (Vernooy et al. 2010). Most of the interest in international biodiversity research is from the academic sector, not commercial companies. The stated goals of this academic research are the generation of greater knowledge and scholarly publications in taxonomy, chemistry, ecology, ecosystems science and related fields such as ethnobotany, in this case. History has shown that intentionally or not, some non-commercial research projects have uncovered potential commercial value. This has led many to conclude that commercial and non-commercial research can no longer be distinguished *a priori* and should therefore be treated as a single indivisible enterprise in the negotiation of ABS agreements. However, non-commercial research is at the core of one CBD objective (the conservation of biological diversity) and provides the basis for another (sustainable use of biodiversity). Indeed, the Nagoya Protocol specifically calls on states to "Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through *simplified measures on access for non-commercial research purposes*, taking into account the need to address a change of intent for such research" (*Nagoya Protocol, Article 8(a)*).

To assist in the implementation of the Nagoya Protocol at the moment of its launch, we propose a framework to assist in the negotiation of ABS agreements for non-commercial research. It includes a mechanism to separate non-commercial from commercial projects, or, alternatively, to anticipate potential changes of utilization of genetic resources from non-commercial to commercial research.

Case study: a DNA barcode registry for medicinal plants

We convened an international, multi-stakeholder workshop in Mexico City in 2013 to advance the debate on access to genetic resources and the sharing of benefits as they may relate to an emerging taxonomic tool called DNA barcoding. Representatives from academic, government and non-governmental organizations from 11 countries in the Americas, Europe and Africa participated (see Workshop Participants). Our focus was the design of a negotiating framework for ABS agreements that would enable construction of a species registry for medicinal plants based on "DNA barcodes". DNA barcoding has been used primarily by taxonomists and ecologists for non-commercial research leading to academic publications. However, the barcoding process raises many of the concerns that led to creation of the Nagoya Protocol: expatriation of biological samples, DNA sequencing, the public release of sequence and other data with potential

monetary value, risks of unapproved changes in utilization of genetic resources from academic to commercial, and lack of benefits shared with provider countries.

We selected medicinal plants as the focus because of the diversity of both commercial and non-commercial stakeholders interested in medicinal plants and the global commercial potential of natural health products (NHPs) derived from these species. Because barcoding can unquestionably "utilize" genetic resources for both non-commercial research and commercial activities, ABS agreements that meet the interests of divergent stakeholders will be essential in the development of a registry, especially if plant samples need to cross international borders.

DNA barcodes are short gene sequences taken from a standardized portion of the genome that can be used to identify biological samples to the species level. The gene regions used for animals, plants and fungi were chosen because they evolve fast enough to separate closely related species but slowly enough that the members of any species are identical or nearly identical (Hebert et al. 2003; CBOL Plant Working Group 2009; Hollingsworth 2011; Schoch et al. 2012). As a result, barcode data separate species well but cannot normally diagnose the regions of origin within a species. The standard barcode regions are well-studied and have no known commercial value such as in drug development or GMO foods. DNA sequences from the approved barcode regions are submitted to GenBank or other members of the International Nucleotide Sequence Database Collaborative (INSDC). Each sequence is linked to a voucher specimen whose species identification has been verified by taxonomic experts. These vouchers are available for examination and confirmation in research biorepositories. Barcode sequences are then taken from unidentified samples and compared with the sequences in the GenBank reference library. This makes it possible to identify species using their DNA in an objective, repeatable way, including medicinal plants growing in the field or processed into powdered mixtures such as those found in herbal remedy capsules.

Since barcoding was proposed, a global network of researchers (primarily taxonomists and ecologists) has submitted more than 400,000 standardized high-quality BARCODE records to GenBank. The Consortium for the Barcode of Life (CBOL) created a Database Working Group that developed the BARCODE data standard after a year of community consultation (Hanner and the CBOL Database Working Group 2005). Data records in INSDC that meet this data standard have the reserved keyword "BARCODE". In addition, more than 2 million have been submitted to the Barcode of Life Data Systems (Ratnasingham and Hebert 2007), a public workbench for barcode projects. The International Barcode of Life project (iBOL), led by the University of Guelph in Canada is the largest coordinated barcoding effort, and initiatives have been launched within taxonomic groups (e.g., fish, Steinke and Hanner 2011; birds, Kerr et al. 2007).

DNA barcoding has already been put to use for similar regulatory applications. The US Food and Drug Administration has tested and adopted DNA barcoding as a tool for regulating seafood in the marketplace (Handy et al. 2011). DNA barcodes are also being put to work for the investigation and prosecution of wildlife crimes against endangered species (see Barcode of Wildlife Project). Several barcode-based analyses

of medicinal plants in the marketplace have already been published (Baker et al. 2012; Newmaster et al. 2013), demonstrating how data from taxonomic studies can be used for consumer protection. The Attorney General of New York State recently took legal action against manufacturers for inaccurate labeling of herbal remedies based on DNA barcoding analyses (O'Connor 2015).

Sharing benefits and risks

An objective, reliable registration and identification system for medicinal plants would enable research on their basic biology, ecology and evolution in ways that would support species conservation programs. Provider country partners in the construction of the registry could benefit from training, capacity-building activities, co-authorship and participation in related research networks. The registry could also provide an arena in which a globally sustainable NHP industry can develop and be regulated. The barcode registry could: (1) open markets for wild crafters and local communities by assuring purchasers that their plants belong to the medicinal plant species that have been tested by regulators and approved for trade; (2) assist the NHP industry in establishing measures of quality assurance tied to each species; (3) assist public health agencies in verifying the species they are testing for clinical efficacy; (4) assist regulatory agencies in confirming the accuracy of product labeling; (5) provide customs and trade authorities with tools to monitor cross-border trade; and (6) enhance consumer confidence in the authenticity of the natural health products they purchase. Indeed, the registry would provide all stakeholders with an objective, transparent taxonomic vocabulary for discussing access to genetic resources, monitoring the resulting flow of medicinal plant materials, and enabling informed discussion of benefits generated by each species. Over time, the DNA barcode registry of medicinal plants would grow through the work of globally-distributed taxonomists and conservation biologists and would complement the content and impact of pharmacopeia.

We see three main challenges along the way to attaining these longer-term benefits. First, all stakeholders in provider countries will want assurances that an approved non-commercial research process of creating the registry will not lead to unapproved commercial use of their genetic resources and associated traditional knowledge, whether by domestic or foreign researchers. The fear of unapproved use is greatest for expatriated samples. Second, all stakeholders in both provider and receiver countries will need to stipulate all non-commercial research activities enabled by the agreement and the benefits they can expect to receive from such activities. The Nagoya Protocol articulates an expansive view of benefits which include collaborative research, access to technology, training and other forms of capacity building.

The final challenge in defining reasonable expectations is the delineation of non-commercial versus commercial research (Popp 2012). CBOL convened an international, cross-sectoral workshop on this topic in Bonn, Germany in November 2008. We agree with the findings of that workshop (CBOL 2008; Schindel 2010) and be-

lieve that non-commercial and commercial intent can be separated in the process of negotiating ABS agreements with the aid of our framework. Box 1 presents a list of activities that reflect commercial intent. An agreement to develop a barcode-based registry of medicinal plants could include a statement that these activities will be considered potentially commercial in character. Parties would agree not to participate in any of these activities under the Barcoding agreement, and that interest in initiating any of these would trigger a halt to all research activities and require the parties to negotiate a new ABS agreement based on commercial intent. In our view, this approach is preferable to the pre-negotiation of clauses for a possible shift to commercial intent, which add to the complexity of agreements and delay negotiations. The nature of commercial activities and the scope of potential benefits that may arise are extremely difficult to determine *a priori*.

Since DNA barcoding is currently beyond the technical capabilities of many developing countries, the construction of a reference library will often require international collaboration. Plant material may need to cross national boundaries to reach secure biorepositories and molecular biology labs capable of DNA barcoding. Even if a provider country has a secure repository, participants may decide that there is value in having duplicate specimens in another repository for reasons of security. In addition, providers would have to give permission to sequence the very short DNA barcode regions and agree to release the sequences into a publicly accessible reference library. Each of these conditions could conceivably raise concerns related to "biopiracy". How then could an ABS agreement be negotiated for the relatively straightforward task of characterizing and registering species, while protecting the commercial potential of medicinal plants and the higher-stakes that would be involved in ABS agreements to follow?

A decision-based framework for ABS agreements

To facilitate the process of negotiating and drafting ABS agreements, especially for non-commercial uses of genetic resources, we propose a decision-based framework. The framework guides representatives of provider and user countries through a series of decisions related to real or perceived risks and suggests choices (see examples, Box 2). The structure of the resulting ABS agreement is shown in Box 3. The goal is to develop agreements that are as simple as possible while addressing the needs, constraints and interests of the parties involved in the negotiation. Since relationships may evolve over time, a decision framework must reflect evolving best practices in negotiating ABS agreements (Biber-Klemm et al. 2010) and allow the parties to develop a narrative of the relationship that captures the expectations of all stakeholders, including those not directly party to the agreement. This narrative becomes the preamble to the agreement and the lens through which the terms of the agreement are interpreted and any disputes resolved (Gold and Bubela 2007). By guiding the negotiation and serving as a communications tool, the proposed framework can strengthen the negotiating position of a developing country partner who may have more limited access to legal

advice. It has the added benefit of informing legal counsel from developed country institutions, who may have limited understanding of ABS agreements, of the needs and interests of developing country partners.

We are in the process of developing a software tool that will enable researchers and provider countries to use the decision-based approach we propose here. The tool will use an interview format to guide potential partners, separately and then together, through the identification and resolution of their interests and concerns. This will then enable them to develop specific agreements with the aid of legal counsel, using terms that are compliant with local laws and conditions.

In conclusion, our framework takes a pragmatic and adaptable approach to the negotiation and development of ABS agreements that are specific to non-commercial research. Our framework will reduce the power imbalances in the negotiation of research agreements between institutions in the Global South and Global North and will aid in building ongoing relationships reliant on trust and good faith. In the process, it will develop the necessary capacity in ABS negotiations and will help to overcome the history of mistrust and exploitation in the use of genetic resources. More specifically, the proposed approach will facilitate the success of barcoding initiatives such as the construction of a registry for medicinal plants. Initiatives such as this will support conservation efforts and will serve the interests of stakeholders in biodiversity rich regions.

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Box 1. List of activities that might be prohibited in non-commercial ABS agreements

A. The following actions could be considered indications of commercial intent:

- Negotiation of fees by either party beyond cost-recovery for access to data, technology, or materials resulting from the research;
- Retention of monetary benefits from sale or lease for profit, patenting, or licensing of research results;
- Transfer of material to commercial third parties;
- The filing of a disclosure of invention with an institutional technology transfer office;
- The filing of a patents or other Intellectual Property Right (IPR);
- Intent to investigate commercial applications, contract with a commercial body or entity, or conduct market research;
- Product development or testing of technology or products as part of a wider undisclosed project; or
- Other forms of contractual restrictions on the dissemination and subsequent use of the results.

B. The following actions could be considered contrary to best practices for non-commercial research:

- Restrictions on the release of research findings (e.g., non-disclosure agreements or unwillingness to publish results) if agreement terms are observed;
- Limitations placed on the involvement of provider country researchers in a project as collaborators and co-authors;
- Publication of results without providing pre-publication access to results by designated institutions in the provider country;
- Delays in the public release of data resulting from the research

Box 2. Examples from a decision-based framework for developing ABS agreements

The following excerpts from a larger treatment (in development) demonstrate how a decision-based approach can be used to negotiate terms of an ABS agreement in the

area of international transfer of genetic resources. Decisions shown in brackets arise from higher-level decisions in a multi-level decision tree.

1. Does the provider country have repositories in which voucher specimens can be archived securely and accessed by researchers?
   a. Yes {What in-country access will the users have to voucher specimens? Can some of the vouchers or subsamples be expatriated?}
   b. No, but the provider country is seeking help in developing one {What specific support and capacity-building is sought?}
   c. No {Proceed to next decision}
2. Can voucher specimens be expatriated?
   a. Yes {What access will the provider country have to their voucher specimens?}
   b. Yes, but only if duplicate specimens and/or subsamples remain in-country {What exchange of information will take place to synchronize the data associated with samples from the same voucher?}
   c. Yes, but with monitoring and safeguards against unapproved use {What specific conditions would be acceptable?}
   d. No {How will secure long-term storage and access by the user country be assured?}
3. Where will tissue samples be analyzed?
   a. In a provider country lab {How can in-country lab capabilities be assured? Is additional training needed? What access to analytical results will user countries have?}
   b. In a provider country lab following capacity-building and training {What training and capacity-building is sought?}
   c. In a user country lab with monitoring and safeguards against any use other than barcoding {What specific conditions would be acceptable?}

Box 3. Example of high-level structure for an ABS Agreement Framework.

Each topic area will link to multiple options for consideration and discussion by the intended non-commercial research partners.

Background

1. Identify the Parties to the Agreement (generally at the institutional level)
2. Identify those with interests in the Agreement, including researchers and indigenous/local communities.
3. Which national ABS laws, regulations or ethics/permitting requirements apply, if any?
4. Which agencies/departments administer (3)?
5. Are there requirements for Prior Informed Consent (depends on answers to 2-3)?

Prior Informed Consent

6. What is the general relationship between providers and users concerning international transfer of material (see examples, 2)?
7. What are the overall scientific or other goals of the project, for example:
   a. Bio-conservation Goals;
   b. Taxonomic Goals;
   c. Regulatory Goals.
8. What are the methodological and sampling details, for example:
   a. Taxonomic groups and number of species;
   b. Geographic area, habitats, numbers of collecting sites;
   c. Methods for collection, preservation, etc.

Mutually Agreed Terms

9. Anticipated outputs, outcomes, and impacts, for example:
   a. Curated collections of whole specimens;
   b. Preserved tissue samples;
   c. Publications;
   d. Publicly released data;
   e. Policy and other impacts.
10. Benefits to providers, for example:
   a. New knowledge;
   b. Collaborative research in local priority topics;
   c. Training and capacity development;
   d. Equipment.
11. Roles and Responsibilities of the Parties, for example
   a. Responsibilities for licensing, funding, sample collection, shipping, handling of materials and data, sequencing, storage;
   b. Responsibility for destruction of samples and/or data;
   c. Constraints on replication or transfer of materials.
12. Declaration of non-commercial intent with identification of terms that trigger a change in purpose (See Box 1).
13. Standard legal terms, for example, termination, liability, warranty, jurisdiction.